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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,275	05/25/2005	Benedikt J Brors	VOSS-P01-011	7663
28120	7590	02/25/2008		
ROPES & GRAY LLP PATENT DOCKETING 39/41 ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			EXAMINER SISSON, BRADLEY L	
			ART UNIT 1634	PAPER NUMBER
			MAIL DATE 02/25/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/509,275

**Applicant(s)**

BRORS ET AL.

**Examiner**

Bradley L. Sisson

**Art Unit**

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15, 17 and 18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15, 17 and 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Priority***

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1-15, 17 and 18 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility.

5. Claims 1-15, 17 and 18 are drawn to a method for the quantification of mRNA. As presently worded, the mRNA may well be that associated with an expressed sequence tag, of EST, of which no know use/utility exist. The aspect of quantifying mRNA that has no utility in and of its self does not constitute a substantial real world value for the claimed invention. Further, a review of the disclosure fails to find where such values of any mRNA that has yet to be found useful under 35 USC 101, has in and of its self been found to satisfy the utility requirements.

6. For an invention to be "useful" it must satisfy the utility requirement of section 101, i.e., it has to be (i) specific, (ii) substantial and (iii) credible. As discussed in the utility rejection above, the invention does not satisfy the criteria of utility requirements as not being [specific and substantial]. Therefore, the claims are rejected as non-statutory for failing to comply with 35 USC 101, i.e., not providing a useful, concrete and tangible result.

7. Acknowledgement is made of claim 12, which is drawn to a computer program for performing the method of claims 1 or 2. A computer method for performing the method of claims 1 and 2 does not make either the program or the method of claims 1 and 2 patentable as neither results in a specific, substantial, and credible utility.

8. Acknowledgement is made of claims 13 and 14 being drawn to a "system" for performing the method of claims 1 and 2. Again, the claims are not drawn to any nucleic acid that has a specific, substantial, and credible utility. While the claims do require that there be a known DNA present, such does not require the DNA to be any different or useful from any other known DNA, e.g., a known EST for which no known utility exists.

9. Claims 1-15, 17 and 18 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Response to argument

10. At page 9, bridging to page 11 of the response of 19 November 2007, applicant's representative asserts that (i) the method may be used to measure transcripts of known yeasts, and (ii) the publications of Zhang et al., and Gray et al., point to the utility of arrays.

11. The above argument has been fully considered and has not been found persuasive. As an initial matter, the claims are not limited to the analysis of known yeasts. Further, even if the yeasts are known, the utility must reside, either directly or indirectly, with the claimed method-determining an absolute concentration of one or more mRNA molecules.

12. As noted above, the claimed method fairly encompasses the quantification of mRNA or ESTs, which can be derived from human cells. Here, the nucleotide sequence is known, however, the usefulness of the EST is not known. Quantifying an otherwise non-useful mRNA does not impart a specific, substantial, and credible utility to same.

13. Acknowledgement is made of the submission of the two publications (Zhang et al., and Gray et al.). The situation at hand is analogous to that of *Ex parte Gray* (BPAI, 1989) 10 USPQ2d 1922 where it was held that publications do not qualify as either evidence or expert testimony such as that provided in a declaration under 37 CFR 1.132. As set forth at 1928,

The reason for requiring declaration or affidavit form is to obtain the assurances that any statements or representations made are correct, as provided by 35 U.S.C. 25 and 18 U.S.C. 1001.

The present showing does not provide such assurances.

14. At page 11 of the response, argument is presented that the rejection of claims under 35 USC 112, first paragraph, should be withdrawn in view of the preceding arguments re. the utility rejection, said arguments have not been found persuasive towards the withdrawal of the rejection for as shown above, the rejection of claims under 35 USC 101 has been maintained.

15. For the above reasons and in the absence of convincing evidence to the contrary, the rejection of claims under 35 USC 101 and under 35 USC 112, first paragraph, has been maintained.

***Conclusion***

16. Objections and/or rejections which appeared in the prior Office action and which have not been repeated hereinabove have been withdrawn.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

18. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

20. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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21. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley L. Sisson/  
Primary Examiner, Art Unit 1634